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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,477	04/15/2004	Fabio Soldati	1/1490	8137
28501	7590	04/30/2007		
MICHAEL P. MORRIS			EXAMINER	
BOEHRINGER INGELHEIM CORPORATION			MAEWALL, SNIGDHA	
900 RIDGEURY ROAD				
P. O. BOX 368			ART UNIT	PAPER NUMBER
RIDGEFIELD, CT 06877-0368			1615	
			MAIL DATE	DELIVERY MODE
			04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/825,477	SOLDATI ET AL.
	Examiner	Art Unit
	Snigdha Maewall	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/02/04 and 02/28/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 07/02/2004 and 12/22/2004 is acknowledged.

Claims 1-20 are pending in this application and claims 1-20 will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claims 1, 5, 7, 10, 12 and 13 recite the limitation "DHA" as one of the component in the composition. The abbreviation makes the limitation indefinite since the specific name of the compound is not recited. The interpretation of the abbreviated term is ambiguous and unclear. For the purpose of the examination the abbreviation is translated as "Docosahexaenoic acid".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/53777 ('777).

('777) discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (page 2, paragraph 6 and claim 2). DHA is disclosed on (page 4, paragraph, 4). ('777) further discloses that the composition can be in the form of pill, capsule, tablet, chewable candies form (page 6, paragraph, 6).

Claim Rejections - 35 USC § 103

6. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777).

The teachings of ('777) have been discussed above. ('777) does not teach the specific weight ratios of various components as claimed. However, with respect to the weight ratios of various components, it is the examiners position that such a parameter is within the purview of a skilled artisan by doing experimental manipulation. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-8, 10-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of Uiterwaal et al. (US patent No. 4,710,387).

The teachings of ('777) have been discussed above. ('777) does not teach molybdenum, chromium and iodine in the composition.

Uiterwaal et al. teaches nutritional supplement preparation for pregnant and breast-feeding women based on milk constituents for pregnant and breast feeding women comprising iodine, calcium, phosphorus, various vitamins, chromium and

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molybdenum, niacin and folic acid etc. (see Table A in column 7, claim 5 and 8). Since the composition provides nutritional supplement to pregnant and breast feeding women, it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate nutrients such as iodine, chromium and molybdenum in the composition forwarded by ('777). A skilled artisan would have made a formulation comprising molybdenum, chromium, iodine, vitamins, minerals, niacin, folic acid and DHA with a reasonable expectation of success.

With respect to the weight ratios of various components and amounts, it is the examiners position that such parameters are within the purview of a skilled artisan by doing experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of Uiterwaal et al. (US patent No. 4,710,387) and further in view of DRUGDEVELOPMENT AND INDUSTRIAL PHARMACY, 12(8&9), 1133-1144 (1986) Robert F. Jimerson.

The teachings of ('777) and Uiterwaal et al. have been discussed above. The references do not teach oblong gelatin capsule. However, Robert F. Jimerson discloses soft gelatin capsule. Robert F. Jimerson further disclose that because of their special properties and advantages, soft gelatin capsules are employed for a wide variety of

uses in pharmaceutical industries and are produced in a variety of shapes, sizes, and colors. Their current applications primarily include, oral dosage forms, suppositories and topical products (see page 1134, paragraph 2 and 3).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to make gelatin capsule of the oblong shape since the article teaches that gelatin capsules bear special properties and advantages in pharmaceutical compositions. A skilled artisan would have made gelatin capsule comprising various nutritional components comprising vitamins, minerals, folic acid, biotin and niacinamide with a reasonable expectation of success.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

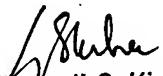
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600